

DETAILED ACTION

Response to Amendment

This office action is responsive to the amendment filed on February 22, 2012. As directed by the amendment: claims 158, 159, 161, 163-167, 170, 175-178, 181, 183, 184, 188, 190, 192, 193, 197-199, 212, 223, 224, and 232 have been amended, claims 1-157, 160, 162, 169, 201-210, 214-222, 230, 233-247 have been canceled, and new claims 248-257 have been added. Thus, claims 158, 159, 161, 163-168, 170-200, 211-213, 223-229, 231, 232, and 248-257 are presently pending in the application.

Election/Restrictions

1. This application contains claims 211- 213, 223-229, 231, 231, 248 and 253-257 drawn to an invention nonelected without traverse in the reply filed on September 23, 2011. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 158, 159, 161, 163-168, 170-175, 179-183, 188, 193-195, 200, and 251 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler (US Patent No. 3,404,681), in view of McNary (US Patent No. 5,899,200).**

As to claim 158, Fowler discloses an inhaler (Fig. 1) comprising: a housing 6 in which container unit 1, containing a medicament formulation, is received and is relatively movable to cause dispensing of a dose of the medicament formulation for inhalation by a user through a dispensing outlet 7 of the housing 6 (col. 4, ln. 17-27); an accessory 28 which is attachable to the housing 6; and a restricting member 30 which is part of the accessory 28 and movable between a first position (removed from the mouthpiece 7) which enables relative movement between the container unit 1 and the housing 6 for dispensing of the dose of the medicament formulation, and a second position (inserted into the mouthpiece 7) in which the restricting member 30 restricts relative movement between the container unit 1 and the housing 6 such that dispensing of the dose of the medicament formulation is prevented (col. 3, ln. 73 – col. 4, ln. 4); wherein when the accessory 28 is attached to the housing 6 the restricting member 30 enters the housing 6 through the dispensing outlet 7 to be disposed in its second position (see Fig. 1). Fowler does not disclose that the restricting member is configured as a clip which in its second position clips to at least one of the housing and the container unit to retain the restricting member in its second position. However, McNary teaches an accessory 9 (cap, Fig. 1) for an inhaler 1 which includes a restricting member 12 configured as a clip (with the provision of detent 13 which effects a snap fit connection between the cap 9 and the housing) and which clips to the housing of the inhaler when in its second, closed position (see Fig. 3, col. 3, ln. 5-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhaler of Fowler so that the restricting member is configured as a

clip as taught by McNary in order to provide a means for keeping the cap in its closed position and preventing the cap from falling out of the housing.

As to claim 159, the modified inhaler of Fowler discloses that the restricting member 30 (Fowler, Fig. 1, Fig. 2) is releasably clipped to the housing 6 in its second position (as modified by McNary's detent 13 (see Fig. 1)).

As to claim 161, the modified inhaler of Fowler discloses that the accessory 28 is attachable to the dispensing outlet 7 of the housing 6 (see Fig. 1 of Fowler).

As to claim 163, the modified inhaler of Fowler discloses that the accessory 28 is a closure positionable to close the dispensing outlet 7 (see Fig. 1 of Fowler) and wherein when the closure is positioned to close the dispensing outlet 7, the restricting member 30 provided on the closure 28 enters the housing 6 through the dispensing outlet 7 to be disposed in its second position (see Fig. 1 of Fowler).

As to claim 164, the modified inhaler of Fowler discloses that in use the dose of the medicament formulation is dispensed from the container unit 1 when the container unit 1 moves relative to the housing 6 in a first direction (col. 4, ln. 17-27 of Fowler) and wherein the restricting member in its second position restricts movement of the container unit 1 in the first direction (col. 3, ln. 73 – col. 4, ln. 2 of Fowler).

As to claim 165, the modified inhaler of Fowler discloses that in its second position the restricting member 30 restricts relative movement between the container unit 1 and the housing 6 through physical engagement of the restricting member 30 with the container unit 1 (col. 3,ln. 73 – col. 4, ln. 2 of Fowler).

As to claim 166, the modified inhaler of Fowler discloses that the restricting member 30, in its second position, is disposed in front of a leading end of the container unit 1 (see Fig. 1 of Fowler).

As to claim 167, the modified inhaler of Fowler discloses that the housing 6 has an axis along which the container unit 1 is movable relative to the housing 6 to dispense the dose of the medicament formulation and the restricting member 30, in its second position, extends laterally to the axis to restrict said relative movement (see Fig. 1 of Fowler).

As to claim 168, the modified inhaler of Fowler discloses that the restricting member 30 is configured as an arm structure (arms 32, see Fig. 2, col. 3, ln. 70-73 of Fowler).

As to claim 170, the modified inhaler of Fowler discloses that the container unit 1 is a dispensing container unit having first 3 and second parts 1 which are movable relative to one another, said relative movement causing dispensing of the dose of the medicament formulation from the dispensing container unit, and wherein the housing 6 has a support 10 for supporting the first part 3 of the dispensing container unit in a stationary position relative to the housing 6 so that, in use, the second part 1 is able to move in the housing 6 relative to the first part 3 to dispense the dose of the medicament formulation (col. 4, ln. 11-27 of Fowler), and wherein the restricting member 30, in its second position, restricts the movement of the second part 1 relative to the first part 3 to prevent dispensing of the dose (col. 3, ln. 73 – col. 4, ln. 4 of Fowler).

As to claim 171, the modified inhaler of Fowler discloses that one of the first and second parts is a dispensing outlet member 3 of the dispensing container unit (valve) and the other part is a container member 1 containing the medicament formulation (aerosol can).

As to claim 172, the modified inhaler of Fowler discloses that the first part is the dispensing outlet member 3 and the second part is the container member 1 and wherein the support 10 is adapted in use to direct the output of the dispensing outlet member 3 out of the housing 6 through the dispensing outlet 7 thereof (col. 4, ln. 21-27 of Fowler).

As to claim 173, the modified inhaler of Fowler discloses that the inhaler is a pressurized metered dose inhaler (pMDI) with the second part 1 being a pressurized container member containing therein the medicament formulation under pressure and the first part being a valve stem 3 of a metering valve for releasing a metered dose of the pressurized medicament formulation from the dispensing container unit upon relative movement between the pressurized container member and the valve stem (col. 4, ln. 12-27 of Fowler).

As to claims 174 and 175, the modified inhaler of Fowler discloses that the support 10 is a stem block for receiving the valve stem 3 (see Fig. 1, col. 3, ln. 59-60 of Fowler) and that the restricting member 30 comprises a pair of arms 32 (Fig. 2 of Fowler) that straddle the support 10 when the restricting member 30 is in the second position (col. 4, ln. 4-6 of Fowler).

As to claim 179, the modified inhaler of Fowler discloses that the closure 28 is movable between a closing position (Fig. 1 of Fowler), engaged with the housing 6, in

which it closes the dispensing outlet 7 and places the restricting member 30 in the second position (col. 3, ln. 73 – col. 4, ln. 4 of Fowler), and an opening position in which it opens the dispensing outlet 7 and places the restricting member 30 in its first position (col. 4, ln. 11-12 of Fowler).

As to claim 180, the modified inhaler of Fowler discloses that the closure 28 is detachably mountable on the housing 6 (col. 4, ln. 11-12 of Fowler).

As to claim 181 and 183, the modified inhaler of Fowler discloses that the closure 28 is detachably mountable on the housing, is releasably engageable with the dispensing outlet 7 of the housing 6 to close the dispensing outlet 7 and that in use the closure 28 is moved from its closing position to its opening position by detaching the closure 28 from the housing 6 (col. 4, ln. 11-12 of Fowler).

As to claim 182, the modified inhaler of Fowler discloses that the closure 28 is releasably engageable with the dispensing outlet 7 of the housing 6 to close the dispensing outlet 7 (col. 3, ln. 73 - col. 4, ln. 2 of Fowler).

As to claim 188, the modified inhaler of Fowler discloses that the container unit 1 further has a metering mechanism 3 for dispensing a metered dose of the medicament formulation on movement of the container unit 1 relative to the housing 6 (col. 4, ln. 12-27 of Fowler).

As to claim 193, the modified inhaler of Fowler discloses that the dispensing outlet 7 of the housing 6 is a nozzle configured for insertion into a mouth of a human (mouthpiece 7, see Fig. 1 of Fowler, col. 3, ln. 46).

As to claim 194, the modified inhaler of Fowler discloses the claimed invention except that the inhaler has a connector which connects the housing and the closure to one another. However, McNary teaches a connector 10 which connects a closure 12 to a housing of an inhaler 1 (col. 2, ln. 46-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhaler of Fowler to include the connector as taught by McNary in order to prevent loss of the closure.

As to claim 195, the modified inhaler of Fowler discloses that the connector is extensible (see McNary, col. 2, ln. 49-52).

As to claim 200, the modified inhaler of Fowler discloses that the connector is a strap 10 (see McNary, col. 2, ln. 46-49).

As to claim 251, the modified inhaler of Fowler discloses that wherein to move the restricting member 30 from the first position to the second position (closing the cap) involves moving the restricting member 30 through the dispensing outlet 7 in a first direction (see Fig. 1), wherein to move the restricting member 30 from the second position to the first position (removing the cap) involves moving the restricting member 30 through the dispensing outlet 7 in a second, opposite direction, and wherein when the restricting member 30 is in the second position, the clip (as modified by McNary's detent 13, see Fig. 1 of McNary) acts to inhibit movement of the restricting member in the second direction (see col. 3, ln. 10-15 of McNary which describes that the cap makes a snap fit connection with the outlet as a result of detent 13).

4. Claims 158, 163, 170, 176-178, 194, and 197-199 are rejected 35 U.S.C. 103(a) as being unpatentable over Ryden (US Patent No. 3,622,053), in view of Meshberg (US Patent No. 6,382,463).

As to claim 158, Ryden discloses an inhaler (Fig. 1-4) comprising: a housing 10, 12 in which a container unit 2, containing a medicament formulation, is received and is relatively movable to cause dispensing of a dose of the medicament formulation for inhalation by a user through a dispensing outlet 34 of the housing 10, 12 (col. 3, ln. 35-41); an accessory 40 which is attachable to the housing 10, 12; and a restricting member 44 which is part of the accessory and movable between a first position which enables relative movement between the container unit 2 and the housing 10, 12 for dispensing of the dose of the medicament formulation (col. 3, ln. 32-41), and a second position in which the restricting member 44 restricts relative movement between the container unit 2 and the housing 10, 12 such that dispensing of the dose of the medicament formulation is prevented; wherein when the accessory 40 is attached to the housing 10, 12, the restricting member 44 enters the housing 10, 12 through the dispensing outlet 34 to be disposed in its second position (col. 3, ln. 20-24). Ryden does not disclose that the restricting member is configured as a clip which, in its second position, clips to the housing and/or the container unit to retain the restricting member in its second position. However, Meshberg teaches a restricting member which is configured as a clip which clips into the housing to retain the restricting member in its closure position (projection 915 clips into recess 917, see Fig. 5, col. 3, ln. 56-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the inhaler of Ryden so that the restricting member is configured as a clip as taught by Meshberg in order to provide a means for retaining the restricting member in place in its closure position and to prevent the closure from falling loose.

As to claim 163, the modified inhaler of Ryden discloses that the restricting member 44 is provided on a closure 40 positionable to close the dispensing outlet 34 and wherein when the closure is positioned to close the dispensing outlet 34, the restricting member 44 enters the housing 10, 12 through the dispensing outlet 34 to be disposed in its second position (see Fig. 2, col. 3, ln. 20-24 of Ryden).

As to claim 170, the modified inhaler of Ryden discloses that the container unit 2 is a dispensing container unit 2 having first 6 and second parts 2 which are movable relative to one another, said relative movement causing dispensing of the dose of medicament formulation from the dispensing container unit 2, and wherein the housing 10, 12 has a support 24 for supporting the first part 6 in a stationary position relative to the housing 10, 12 so that in use, the second part 2 is able to move in the housing 10, 12 relative to the first part 6 to dispense the dose of medicament formulation, and wherein the restricting member 44, in its second position, restricts movement of the second part 2 relative to the first part 6 to prevent dispensing of the dose (see Fig. 2, col. 3, ln. 20-24 of Ryden).

As to claim 176-178, the modified inhaler of Ryden discloses that the clip detachably engages a step in the support of the housing when in the second position

and wherein the step is in a surface of the housing on which the support is provided (Meshberg teaches the clip engaging the nozzle outlet, see Fig. 5, col. 3, ln. 56-62).

As to claim 194, the modified inhaler of Ryden discloses a connector 46, 47 which connects the housing 10, 12 and the closure 40 to one another (see Fig. 3, col. 3, ln. 5-8 of Ryden).

As to claim 197, the modified inhaler of Ryden discloses that the connector 46, 47 comprises: a first component (recesses in walls 36, 38, see Fig. 3, col. 3, ln. 7-8 of Ryden), attached to the housing 10, 12; and a second component 46, 47, attached to the closure 40; wherein the components are capable of relative movement between a contracted position, in which the closure 40 closes the dispensing outlet 34, and an extended position, in which the closure 40 is spaced from the dispensing outlet 34 (see Fig. 2 of Ryden).

As to claim 198, the modified inhaler of Ryden discloses that one of said components comprises a pin 46, 47 and the other comprises a slot (recesses in wall 36, 38, see Fig. 3 of Ryden), wherein the pin 46, 47 is captive within the slot and capable of movement within it (col. 3, ln. 5-8 of Ryden).

As to claim 199, the modified inhaler of Ryden discloses that at least one of the components comprises hinging means (Fig. 2, col. 3, ln. 5-8 of Ryden).

5. **Claims 184-187, 189-192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler, in view of McNary, as applied to claims 158 and 163 above, and further in view of Marx (US Patent No. 7,464,708).**

As to claims 184-186 and 189, the modified inhaler of Fowler discloses the claimed invention except that the inhaler further comprises an indicator in the container unit with a visual display wherein the indicator is adapted to update the visual display in response to movement of the container unit relative to the housing. However, Marx teaches an inhaler 100 (Fig. 8a) with an indicator 50 (Fig. 4, Fig. 7) on a container unit 1 of the inhaler and which includes a visual display (at 67, Fig. 5) wherein the indicator 50 updates the visual display 67 in response to movement of the container unit 1 relative to the inhaler housing 20 (col. 16, ln. 12-24).

As to claim 187, the modified inhaler of Fowler discloses the claimed invention including that the restricting member in its second position restricts movement of the container unit and the housing such as to prevent updating of the display (since Fowler's restricting member 30 prevents the container 1 from being moved relative to the housing 6, it would also prevent updating of the display).

As to claims 190-192, the modified inhaler of Fowler discloses the claimed invention including that the indicator is mounted on the container member of the container unit, the indicator is mounted at the leading end of the container unit and that the indicator is comprised in the second part of the container unit (see Fig. 4, Fig. 7 of Marx).

6. Claims 194 and 196-199 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler, in view of McNary, as applied to claims 158 and 163 above, and further in view of Arghyris et al (US Patent No. 6,261,274).

As to claim 194, the modified inhaler of Fowler discloses the claimed invention except that the inhaler has a connector which connects the housing and the closure to one another. However, Arghyris teaches a connector 22 which connects a closure 21 to a housing of a dispenser (col. 5, ln. 7-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhaler of Fowler to include the connector as taught by Arghyris in order to prevent loss of the closure.

As to claim 196, the modified inhaler of Fowler discloses that the connector is telescopic (see Arghyris, col. 5, ln. 16-21).

As to claim 197, the modified inhaler of Fowler discloses that the connector 22 (Fig. 3 of Arghyris) comprises: a first component 25, attached to the housing; and a second component 22, attached to the closure 21; wherein the first and second components are capable of relative movement between a contracted position, in which the closure 21 closes the dispensing outlet 9 (Fig. 1), and an extended position, in which the closure 21 is spaced from the dispensing outlet 9 (see Fig. 2, Fig. 3, col. 5, ln. 7-21).

As to claim 198, the modified inhaler of Fowler discloses that one of said components comprises a pin 22 and the other comprises a slot 25, wherein the pin is captive within the slot and capable of movement within it (see Fig. 3 of Arghyris).

As to claim 199, the modified inhaler of Fowler discloses that at least one of the first and second components comprises a hinge (see Arghyris, col. 5, ln. 17-18).

Allowable Subject Matter

7. Claims 249, 250, and 252 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed February 22, 2012 with respect to the Meshberg reference have been fully considered but they are not persuasive.

Applicant argues on page 13 of the remarks that Meshberg does not disclose the projection 915 having any attributes of a clip and therefore, does not teach a clip as required by the claims. However, the argument is not well taken because taking the definition of a clip to be "any of various devices for gripping or holding things together; a clasp or fastener" (The American Heritage® Dictionary of the English Language, Fourth Edition copyright ©2000 by Houghton Mifflin Company. Updated in 2009. Published by Houghton Mifflin Company), Meshberg's projection 915 (Fig. 5) engages recess 917 for the purpose of holding the closure in place on the nozzle 6 and therefore, can be said to be configured as a clip as the claim requires.

9. Applicant's arguments with respect to claim 15 with regards to the Fowler reference have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection since McNary, and not Fowler,

is cited as teaching the newly added elements of the claim which the arguments are directed towards.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE L. SKORUPA whose telephone number is (571)270-1479. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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